After entry of this Amendment, the pending claims are claims 1-17, 20-31, 34-38 and 43-45.

The Office Action dated October 20, 2008 has been carefully considered. Claims 18, 19, 32, 33 and 39-

42 were previously canceled. Claims 1-17, 20-31, 34-38 and 43-45 have been amended. Claims 3-5,

10, 20-24 and 34-38 were previously withdrawn as being drawn to a non-elected species based on the

understanding that the claims would only be restricted to the elected species if no generic claim is held

allowable. Claims 1-17, 20-31, 34-38 and 43-45 have been amended to make explicit what was already

implicit. Specifically, claims 1-17, 20-31, 34-38 and 43-45 have been amended to recite a bone fastener

implantation and removal system. Support for the amendments to these claims can be found throughout

the specification and drawings and, specifically, in Specification Paragraph Nos. 39, 41, 52, 55 and 57

and Figs. 2, 7a, 7b and 11a-12. Accordingly no new matter has been added to the application as a result

of the above-described amendments. Applicants respectfully request reconsideration and allowance of

the present application in view of the above Amendments and the following remarks.

In the Final Office Action dated October 10, 2008, the Examiner:

• rejected claims 1, 2, 6-9, 11, 12, 14-17, 25-31 and 43-45 under 35 U.S.C. 102(b) as

being anticipated by U.S. Patent No. 6,148,699 to Han ("Han"); and

rejected claim 13 under 35 U.S.C. 103(a) as being unpatentable over Han in view of

U.S. Patent Application Publication No. 2002/0188301 to Dallara et al. ("Dallara").

**INDEPENDENT CLAIM 1** 

Independent claim 1 and claims 2, 6-9, 11, 12 and 14-17, which are dependent therefrom have

been rejected as being anticipated by Han. Dependent claim 13 has been rejected as being unpatentable

over Han in view of Dallara. Applicants respectfully traverse these rejections with respect to the above-

listed claims, as amended.

Referring to Figs. 1-3, Han discloses a screwdriver including a shaft 14 having a handle 12

affixed thereto at one end and a drive bit 16 for engaging a screw at the other end. The screwdriver

further includes a screw engaging device 20 that is slidably disposed about the shaft 14 and engages the

screw. The screw engaging device 20 includes a main sleeve 40 having an outer threaded portion 42 at

its rear end, for engaging an end sleeve 50. The main sleeve 40 also includes a pair of slots 43 formed

therein that receive L-shaped brackets 22, 28. In use, the main sleeve 40 and end sleeve 50 are slidably

disposed on the shaft 14 with the end sleeve 50 rotatably coupled to the main sleeve 40. The two L-

shaped brackets 22, 28 are then inserted into the slots 43 formed in the main sleeve 40. The end sleeve

50 is rotated so that the end sleeve 50 contacts the L shaped brackets 43, 48. Rotation of the end sleeve

50 with respect to the main sleeve 40 adjusts the desired depth that the drive bit 16 is received within the

main sleeve 40.

Amended claim 1 is directed to a bone fastener implantation and removal system and recites as

follows:

a bone plate including a top surface, a bottom surface and a plurality of fastener holes extending from the top surface to the bottom surface; a plurality of fasteners

receivable within the fastener holes formed in the bone plate; and a tool including: a

drive shaft having proximal and distal ends, an intermediate portion, an outer sleeve engaging portion and a length; a handle portion associated with the drive shaft proximal end; a fastener engaging portion associated with the drive shaft distal end, the fastener engaging portion comprising a first surface configured to axially engage one of the plurality of fasteners and a second surface configured to rotationally engage the fastener; and an outer sleeve associated with the drive shaft intermediate portion, the sleeve comprising a proximal end, a distal end and a drive shaft engaging portion, the distal end contacting the top surface of the bone plate to facilitate removal of the fasteners from the fastener holes; wherein the outer sleeve engaging portion and the drive shaft engaging portion are configured to coact to allow at least a portion of the drive shaft to translate linearly within the sleeve. (Emphasis Added).

Applicants respectfully submit that there is no disclosure, teaching, or suggestion in Han of a bone fastener system comprising a bone plate including a top surface, a plurality of fasteners and a tool including a drive shaft having proximal and distal ends, an intermediate portion, an outer sleeve engaging portion, a fastener engaging portion associated with the drive shaft distal end, the fastener engaging portion comprising a first surface configured to axially engage one of the plurality of fasteners and a second surface configured to rotationally engage the fastener; and an outer sleeve associated with the drive shaft intermediate portion, the sleeve comprising a proximal end, a distal end and a drive shaft engaging portion, the distal end contacting the top surface of the bone plate to facilitate removal of the fastener from the fastener hole. Han, at best, discloses a shaft 14 having a drive bit 16 for engaging a screw, a screw engaging device 20 slidably disposed about the shaft 14 and configured to engage the screw. The screw engaging device 20 including a main sleeve 40, an end sleeve 50 and a pair of L shaped brackets 22, 28 disposed between the main sleeve 40 and the end sleeve 50. The end sleeve 50 is rotatably coupled to the main sleeve 40. There is no disclosure, teaching or suggestion in Han of a tool having an outer sleeve contacting the top surface of the bone plate to facilitate removal of a fastener

called fastener driving portion. As such, it cannot contact the bone plate.

Therefore, for at least the reason identified above, it is respectfully submitted that Han does not

disclose, teach, or suggest all of the limitations of independent claim 1. Withdrawal of this rejection and

allowance of independent claim 1 is respectfully requested.

Furthermore, as claims 2, 6-9, 11, 12 and 14-17 all depend from independent claim 1, it is

submitted that these claims are equally allowable. Withdrawal of these rejections and allowance of

claims 2, 6-9, 11, 12 and 14-17 is also respectfully requested.

With respect to claim 13 which was rejected under 35 U.S.C. 103(a) as being unpatentable over

Han in view of Dallara, it is respectfully submitted that Dallara does not overcome the shortcomings of

Han. Dallara was cited for the proposition that it would be obvious for one of ordinary skill in the art to

incorporate a roughened surface. Without addressing the merits of this argument, it is respectfully

submitted that, for at least the above-identified reason, neither Han nor Dallara, either alone or in

combination, disclose, teach or suggest all of the limitations of dependent claim 13 and, specifically, the

above-listed features of claim 1. Thus, it is respectfully submitted that dependent claim 13 is allowable

over the cited prior art. Withdrawal of this rejection and allowance of dependent claim 13 is respectfully

requested.

Moreover, claims 3-5, 10 and 20-24 were withdrawn as being directed to a non-elected species

based on the understanding that the claims would only be restricted to the elected species if no generic

claim is held allowable. It is respectfully submitted that independent claim 1 is generic and, as such, claims 3-5, 10 and 20-24 should be allowed as well.

## **INDEPENDENT CLAIM 25**

Independent claim 25 and claims 26-31, which are dependent therefrom, have been rejected as being anticipated by Han. Applicants respectfully traverse these rejections with respect to the above-listed claims, as amended.

Amended independent claim 25 is directed to a bone fastener implantation and removal system and recites as follows:

a bone plate including a top surface, a bottom surface and a plurality of fastener holes extending from the top surface to the bottom surface; a plurality of fasteners receivable within the fastener holes formed in the bone plate; and a tool including: a drive shaft having a fastener engaging end and a sleeve engaging portion, the fastener engaging end comprising a rotational engagement portion and an axial engagement portion; a sleeve disposed about at least a portion of the drive shaft, the sleeve comprising a proximal end, a distal end and a drive shaft engaging portion, the distal end contacting the top surface of the bone plate to facilitate removal of one of the plurality of fasteners from the fastener holes; wherein the sleeve engaging portion and the drive shaft engaging portion comprise complementary threads configured to allow the drive shaft to translate linearly within the sleeve when the drive shaft is rotated relative to the sleeve. (Emphasis Added).

For reasons similar to those described above in connection with independent claim 1, it is respectfully submitted that Han does not disclose, teach or suggest a bone fastener system comprising a bone plate including a top surface, a plurality of fasteners and a tool including a drive shaft having a fastener engaging end and a sleeve engaging portion, the fastener engaging end comprising a rotational engagement portion and an axial engagement portion; a sleeve disposed about at least a portion of the

drive shaft, the sleeve comprising a proximal end, a distal end and a drive shaft engaging portion, the

distal end contacting the top surface of the bone plate to facilitate removal of one of the plurality of

fasteners from the fastener holes. Han, at best, discloses a shaft 14 having a drive bit 16 for engaging a

screw and a screw engaging device 20 slidably disposed about the shaft 14 and configured to engage the

screw. The screw engaging device 20 including a main sleeve 40, an end sleeve 50 and a pair of L

shaped brackets 22, 28 disposed between the main sleeve 40 and the end sleeve 50. The end sleeve 50 is

rotatably coupled to the main sleeve 40. There is no disclosure, teaching or suggestion in Han of a tool

having a sleeve for contacting the top surface of the bone plate to facilitate removal of a fastener from a

fastener hole. The distal end of the so-called sleeve in Han is rotatably coupled to the so-called fastener

engaging end. As such, it cannot contact the bone plate.

Therefore, for at least the reasons identified above, it is respectfully submitted that Han does not

disclose, teach, or suggest all of the limitations of independent claim 25. Withdrawal of this rejection

and allowance of independent claim 25 is respectfully requested.

Furthermore, as claims 26-31 all depend from independent claim 25, it is submitted that these

claims are equally allowable. Withdrawal of these rejections and allowance of claims 26-31 is also

respectfully requested.

Moreover, claims 34-38 were withdrawn as being directed to a non-elected species based on the

understanding that the claims would only be restricted to the elected species if no generic claim is held

allowable. It is respectfully submitted that independent claim 25 is generic and, as such, claims 34-38

should be allowed as well.

## **INDEPENDENT CLAIM 43**

Independent claim 43 and claims 44 and 45, which are dependent therefrom have been rejected as being anticipated by Han. Applicants respectfully traverse these rejections with respect to the above-listed claims, as amended.

Amended independent claim 43 is directed to a bone fastener implantation and removal system and recites as follows:

a bone plate including a top surface, a bottom surface and a plurality of fastener holes extending from the top surface to the bottom surface; a plurality of bone fasteners receivable within the fastener holes formed in the bone plate; and a tool including: an inner shaft for engaging one of the bone fasteners, an outer shaft for engaging the bone fastener, and an outer sleeve for contacting the top surface of the bone plate; wherein the inner shaft is configured to axially engage the bone fastener and is slidably disposed within the outer shaft; wherein the outer shaft is configured to rotationally engage the bone fastener and further comprises an outer sleeve engaging portion; and wherein the outer sleeve further comprises an outer shaft engaging portion such that the outer shaft may translate linearly within the outer sleeve when the outer sleeve engaging portion rotationally engages the outer shaft engaging portion. (Emphasis Added).

For reasons similar to those described above in connection with independent claim 1, it is respectfully submitted that Han does not disclose, teach or suggest a bone fastener system comprising a bone plate including a top surface, a plurality of fasteners and a tool including and a tool including an inner shaft for engaging one of the bone fasteners, an outer shaft for engaging the bone fastener, and an outer sleeve for contacting the top surface of the bone plate. Han, at best, discloses a shaft 14 having a drive bit 16 for engaging a screw and a screw engaging device 20 slidably disposed about the shaft 14 and configured to engage the screw. The screw engaging device 20 including a main sleeve 40, an end sleeve 50 and a pair of L shaped brackets 22, 28 disposed between the main sleeve 40 and the end sleeve

50. The end sleeve 50 is rotatably coupled to the main sleeve 40. There is no disclosure, teaching or

suggestion in Han of a tool Having an outer sleeve for contacting the top surface of the bone plate.

Therefore, for at least the reasons identified above, it is respectfully submitted that Han does not

disclose, teach, or suggest all of the limitations of independent claim 43. Allowance of independent

claim 43 is respectfully requested.

Furthermore, as claims 44 and 45 both depend from independent claim 43, it is submitted that

these claims are equally allowable. Allowance of claims 44 and 45 is also respectfully requested.

## **CONCLUSION**

Based upon the above-listed amendments and remarks, Applicants respectfully submit that the present application, including claims 1-17, 20-31, 34-38 and 43-45, is in condition for allowance and

such action is respectfully requested.

A fee of \$810.00 is believed due for this submission for the filing of a Request for Continued

Examination. The Commissioner is authorized to charge these and any other fees which may now or

hereafter be due in this application to Deposit Account No. 19-4709.

In the event that there are any questions, or should additional information be required, please

contact Applicant's attorney at the number listed below.

Respectfully submitted,

Date: December 8, 2008

/Giuseppe Molaro/

Giuseppe Molaro Registration No. 52,039

For: Brian M. Rothery Registration No. 35,340

Attorney for Applicants
Stroock & Stroock & Lavan LLP

180 Maiden Lane

New York, New York 10038

(212) 806-6114